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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,435	06/30/2001	A. Francis Stewart	9882-012	8975
759	90 09/22/2004		EXAM	INER
Craig J. Arnold, Esq. AMSTER, ROTHSTEIN & EBENSTEIN LLP			MCGARRY, SEAN	
90 Park Avenue		IEIN LLP	ART UNIT	PAPER NUMBER
New York, NY	10016		1635	,
			DATE MAIL ED. 00/22/2007	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/895,435	STEWART ET AL.
Office Action Summary	Examiner	Art Unit
	Sean R McGarry	1635 .
The MAILING DATE of this communicating Period for Reply	ion appears on the cover sheet with th	e correspondence address
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICAT  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communication of the period for reply specified above is less than thirty (30) day if NO period for reply is specified above, the maximum statuton. Failure to reply within the set or extended period for reply will, the Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	FION.  CFR 1.136(a). In no event, however, may a reply button.  ys, a reply within the statutory minimum of thirty (30)  y period will apply and will expire SIX (6) MONTHS for  by statute, cause the application to become ABANDO	e timely filed  days will be considered timely. rom the mailing date of this communication.  DNED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed or	n <u>09 June 2004</u> .	
·— ·	This action is non-final.	
3) Since this application is in condition for a closed in accordance with the practice u		
Disposition of Claims		
4) ⊠ Claim(s) <u>1-5,11-20 and 53-74</u> is/are pen 4a) Of the above claim(s) is/are w 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-5,11-20,53-55,57-60,62-65 a</u> 7) ⊠ Claim(s) <u>56,61 and 66</u> is/are objected to 8) □ Claim(s) are subject to restriction	rithdrawn from consideration.  nd 67-74 is/are rejected.	
Application Papers		
9) The specification is objected to by the Ex		
10) The drawing(s) filed on is/are: a)[	• • • • • • • • • • • • • • • • • • • •	
Applicant may not request that any objection	- · ·	` '
Replacement drawing sheet(s) including the 11) The oath or declaration is objected to by		•
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for f a) All b) Some * c) None of:  1. Certified copies of the priority doc 2. Certified copies of the priority doc 3. Copies of the certified copies of the application from the International * See the attached detailed Office action for	uments have been received. uments have been received in Applic ne priority documents have been rece Bureau (PCT Rule 17.2(a)).	cation No eived in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-93) Information Disclosure Statement(s) (PTO-1449 or PTO Paper No(s)/Mail Date		il Date al Patent Application (PTO-152)
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## **DETAILED ACTION**

Claims 1-5, 11-20, 53-55, 57-60, 62-65, and 67-74 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed 6/8/04 introduces new matter into the disclosure. The added material which is not supported by the original disclosure is as follows: The language introduced into the claims refers to functional variants that alter SEQ ID NO: 3 only in the central crossover region and also refers to inverted repeat alterations at this location. Applicant has pointed to page 5 of the specification. It is noted that nowhere one page 5 is there a reference to crossover region modifications or inverse repeat modifications in the context of the claimed invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 1-5, 11-13, 15-20, 54, 55, 57, 59, 60, 64, 65, and 67 remain and new claims 68-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO:3 which corresponds to the cDNA/genomic DNA encoding the human/rat/mouse species of TRT promoter and SEQ ID NO: 2 which corresponds to TRT'. SEQ ID NO: 3 and SEQ ID NO: 2 meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass "functional variants thereof" which may correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), functional variants that are altered from SEQ ID NO: 3 only in the crossover region including, but not limited to inverted repeat, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. It is noted that applicant's specification provides a description of what might be a "functional variant" at pages 6 and 11, for example. Applicant description/definition requires only that at least some change in sequence is made. There is no upper limit to the changes and the functional variants read on species with no apparent structural similarity as SEQ ID NO: 2 or 3 but which would have the same function. It is noted that the specification provides a few examples, but only examples where the structure is quite similar to that of SEQ ID NO:2 or 3 for example. The specification provides a method to screen for

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functional variants. The specification provides potential methods for finding species of the claimed invention, but fails to provide the structure of these species.

<u>Vas-Cath Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.)

With the exception of SEQ ID NO: 3 or 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, <u>University of California v. Eli Lilly and Co.</u>, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can

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clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a

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process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 3 or 2 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that <u>Vas-Cath</u> makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant argues that the invention is now limited to functional variants where the variants differ from SEQ ID NO: 3 only in the crossover region. Applicant asserts that such functional variants are within the scope of the invention and that such variants are

Applicants arguments filed 6/08/04 have been considered but are not persuasive.

sufficiently described at page 5 of the specification. It is noted that there is no disclosure

of a central crossover region in the context of the claimed invention on page 5. There

are no functional variants disclosed that posses the requisite function of the exemplified nucleic acids. The declaration of Bernard Hallet does not take the place of an adequate description of the invention in the specification. It is again noted that **regardless of the complexity or simplicity of the method of isolation.** Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See <u>Fiers v. Revel</u>, 25 USPQ2d 1601, 1606 (CAFC 1993). Applicant is reminded that <u>Vas-Cath</u> makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) So, although the declaration might provide evidence of enablement for a particular embodiment, it does not remedy the lack of an adequate written description of the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 11-13, 53, 55, 58, 60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mahillon et al [NAR Vol. 16(24):1988].

Mahillon et al disclose a pGI2 plasmid sequence (a vector with sequences other than Tn4430 (ie "heterologous" as defined in the instant specification at page 6, for example)). The sequence includes SEQ ID NO:3 and SEQ ID NO:2 and does not

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contain more than 200 contiguous nucleotides of SEQ ID NO: 4. The pGI2 plasmid was cloned and characterized in E.coli cells.

Claims 1-3, 11-13, 53, 55, 58, and 60 remain under 35 U.S.C. 102(b) as being anticipated by Mahillon et al [The EMBO Journal Vol. 7(5):1515-1526, 1988].

Mahillon et al have disclosed several plasmid vectors that comprises SEQ ID NO: 3 and SEQ ID NO: 2 while not comprising more 100 contiguous nucleotides of SEQ ID NO: 4. Mahillon et al have disclosed that the plasmid vectors have various selectable markers which of themselves would be "heterologous" nucleic acid sequences as defined in the instant specification (see page 6, for example).

Claims 20, 63, and 65 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mahillon et al [The EMBO Journal Vol. 7(5):1515-1526, 1988].

Mahillon et al is relied upon as above. Additionally Mahillon et al disclose that the vectors described encode Tnpl and further the plasmids are in E. coli cells which are capable of expressing such heterologous proteins from vectors. Although not specifically disclosed in the reference it would appear inherent in the reference that the disclosed compositions/compounds in [a] container/s since one would keep such compositions in a container to keep the experimental compounds free from contamination, to minimize loss due to evaporation, or to keep them [the experimental

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compounds] from covering a work area, for example. If the compositions/compounds disclosed in the reference were not in containers it would have been obvious to do so for the same reasons above where inherency has been presumed.

Applicants arguments filed 6/08/04 have been considered but are not persuasive.

Applicant argues that the prior art contains all 249 nucleotides of SEQ ID NO: 4 and provides sequences as evidence. These sequences are not convincing since these sequences are not those sequences of the prior art applicant is provided as an attachment to this Official Action an alignment of the prior art reference and SEQ ID NO: 4 of the instant application. It is clear that neither sequence contains more than 200 contiguous nucleates of SEQ ID NO: 4. Applicant argues that one would not provide the possible constituents of the claimed kits in separate containers. It is noted that the rejection of record clearly set forth the reasons for storage in a container or containers. Applicant argues as if the only other possible constituent is a Tnpl protein. This is not the case since the invention also considers a cell capable of expressing a Tnpl protein, for example.

Claims 56, 61, and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sean R McGarry Primary Examiner Art Unit 1635

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ALIGNMENTS

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Stewart, P.A., Zhang, Y. and Mallet, B. Use of a tyrosine recombinase For genetic engineering Patent: MO 03004652-A 4 16-JAN-2003; AUTHORA TLYTE SOURNAL

REFERENCE

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/db\_xref="SWISS-PROT:P10020"
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1 (bases 1 to 4149)
Mahillon,J. and Lereclus,D.
Structural and functional analysis of Th4430: identification of integrase-like protein involved in the co-integrate-resolution linear Data kindly reviewed (03-APR-1989) by Lereclus Location/Qualiflers 1. .4149 | Organisme" Bacillus thuringiensis" | Mol type="genomic DNA" | Graine "Hill" BITIN4430 4149 bp DNA Bacillus thuringiensis transposon Tn4430. /transl\_table=11 /protein\_id="CAA30492.1" /bd\_xref=10:1403492 /db\_xref==COA:110021" /db\_xref==SMISS-PROT:P10021" note="inverted repeat A" /transl\_table=11 /protein\_id="CAA30491.1" /db\_xref="G1:40348" /db\_xref="GOA:P10020" EMBO J. 7 (5), 1515-1526 (1988) 88312602 db xref="taxon:1428" /map="plasmid pG12" /clone\_lib="pBR322"

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| coduct= | table=1|
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| produc
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LSKATOSKERI PTOTKKA SPOSKVKTEKOPI QOMMOVALENDA FFT DEBALFLIRI QRPLAP
KRNCI VNDI HASENAL PMGOKOI ADBLKTDKKI SRI VNGI VOKGYI VKANGHKPEGVK
ARTYALFINPNI I YSGERDNVETTLKAL FMSKSLFKKPPIALF"
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HSKLPR I KLTDLLI EVASWTGFIDQPTHASTNGSPOGESONI VLATLÄAMOTNI GLTK
MAEATPEI SYROMANASOWRMYDDASI LLVNF (VEGSKUSSYWGDGTTS SSDGMR
LSI RANRS LHADDSHYY GTGGGGTI YRPPVSGOLSAXIFWKVI TTNARDALHVLDGLLLHHE
TDLKI EEHYTDTAGYTDQVFALTHLLGFRFAPR I RDLADTKLIFS I PGGEEY RNVQALL
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TLFTLDYISNKAVRRVQKGLNKGEAINALARTIFFGQRGEFRERALQDQLQRASALN
IINAISVWNTVYMEKAVEELKARGEFREDLMPYAWPLGWEHINFLGEYKPEGLHDTG
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serain="thuringiensis H1.1."
db_xref="taxon:1428"
plasmid="pGI2"
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/note="direct repeat 1"
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/note="direct repeat 1"
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/transpogon="Tn4430"
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X13481.1 GI:3171732
X13481.1 GI:3171732

plasmid; plasmid pGI2; recombinase; resolvase; transposase;
transposon; unidentified reading frame.
Bacillus thuringiensis
Bacteria; Firmicutes; Bacillales; Bacillaceae; Bacillus; Bacillus
Bacteria; Firmicutes; Bacillales; Bacillus; Bacillus
Comparagroup.

I (base 1 to 6999)
S Mahillon, J and Seurinck, J.
S Mahillon, J and Seurinck, J.
Complete nucleocide sequence of pGI2, a Bacillus thuringiensis
plasmid containing Th4430
L Nucleic Acids Res. 16 (24), 11827-11828 (1988)
B 89098342
NINRHYYELAALTELRHHIRSGDI FVSGSRHFRAFDDYLI PYDENNEVSNI PNGLTAP
LIKAEDYLTDRINRLARHENGKSKELGEVJOS GOGGLHYRELDROFTSEBRAPSKLL
HSMLEN KLITDLI EVASATGFFIDGFHASTROSPEDSEGNIYLATLAMAGTNIGLTR
MARATPGI SYRQMANASOWRYDDAMVRAGSI LUNPOKEOKLSSYMGDGTTSSSDGNR
LISI AVRSTHADSNIPHTGYGRGGTI YRRYSPOGDASATWYNTITNARDAHTYDGELHHB
TDLKTERHYDDTAGTROGTGTI YRRYSPAGDIASATWYNTITNARDAHTYDGELHHB
TOLKTERHYDDTAGTTOOVPALTHLIGFR FARI RDLADTGLFS PGGESTENVOALL
KGKINVKLI KENYEDIRRLAYSVQTGKVSBALIMGKLGSYARQNKLATALGEMGRIEK
TLFTLDT SIKKAVRRKÄVDERLÄNGEFREDLMPYAMPLGMERHTIFFGGRASALN
I I I INALSVATIYRKÄVDERLÄNGEFREDLMPYAMPLGMEHINFLGSYKFEGLHDTG
OMNLAPLRI KEPPYS"
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Submitted (04-NOV-1988) Mahillon J., Plant Genetics Systems, J
Plateaustraat 22, B-9000 Gent, Belgium
revised by [3]
3 (bases 1 to 9672)
Hoflack, L.
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Best Local Similarity 98.0%; Pred. No. 1.44-31.
Matches 244; Conservative 0; Mismatches 5; Indels
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/note="inverted repeat A'"
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Bacillus thuringiensis
Bacteria, Firmicutes; Bacillales; Bacillaceae; Bacillus; Bacillus
cereus group.
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Bace of a tyrosine/Fecombinese for genetic engineering
Patent: WG 03004652-A 7 16-NAN-2003,
The European Molfcular Biology Laboratory (DE) ; L'Universite
Catholique and Molfcular Est
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Use of a tyrosine recombinase for genetic engineering
Patent: WO 03004652-A 2 16-JAN-2003;
The European Molecular Biology Laboratory (DE); L'Universite
Catholique De louvain (BE)
Location/Qualifiers
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                                                                                                                         1. .118
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Organism="Bacillus thuringiensis"
/mo/ type="unassigned DNA"
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Sequence 7 from Patent W003004652.
Ax671528
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Sequence 8 from Patent W003004652.
Ax671529 Ax671529.1 GI:29329879
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Bacteria; Firmicutes;
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Best Local Similarity 99.11
Matches 115; Confervative
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Matches 118;
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SOURCE
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                      /trānslation="MKKLLISPIAILFFICGFNLKAPAABEIIDYOSLYNOAIOEGVL
DONSVSYNBWLKQNKBEFMPIYODGLKGGVFLEPLESYNBWLKLNNYGOAPTGDIELFD
DYTPRGSWGGFTLKAGDIFITNATESAGIVGHAAIANGDNYILHMPGAGGNUQUSTS
NWWGYKTAAGKWITKYRLKOPILLARDYARYADRNFYSTTGGATKGNYLDYGIDTHLYO
KNPTYCSKLVFQALYFGSGSRNVMQAVSGIVTPYGLIDTFTSAXRPSLVKTY"
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PHKDFRYGGYWLAVYVEGENPDI YYEY SYQDKKVNPQAY FNSEKAI KKKMMGGSGLTE
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/product="put. GIZ site-specific recombinase"
/protein_id="CAA31835.1"
/db_xref="GI:40322"
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/note="unnamed protein product; ORF 3"
/codon_start=1
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Sequence 2 from Patent W003004652.
AX671523.1 GI:29329473
                                                                                                                                                                                                                                     protein_id="CAA31834.1"
|db_xref="GI:40321"
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/transl_table=1;
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